REMARKS

Claims 1, 5, 6, and 61-63 having been amended, and claims 65-75 having been added, the pending claims are 1-3, 5-7, 59, and 61-75.

The deleted subject matter of claims 1 and 6 is now recited in claims 65 and 69, respectively. The additional amendment to claim 6 is supported by the specification at, for instance, page 15, lines 10-27 and page 24, line 18 through page 26, line17.

Claim 61 has been amended to be an independent claim and now incorporates the subject matter of claim 1.

The amendments to claims 62 and 63 are supported by the parent application U.S. Patent Application Serial No. 08/727,084 at SEQ ID NO:4. SEQ ID NO:4 of U.S. Patent Application Serial No. 08/727,084 has been added to the instant application as SEQ ID NO:19.

New claim 65 is supported by the specification at, for instance, Example 7, and by originally filed claim 1.

New claims 66, 67, and 70 are supported by originally filed claims 2, 3, and 7, respectively.

New claim 68 is supported by originally filed claim 5 of the parent application.

New claim 69 is supported by originally filed claim 6, and by the specification at, for instance, page 11, lines 21-35.

New claims 71 and 73 are supported by the specification at, for instance, page 10, line 29 through page 11, line 19.

New claim 72 is supported by the specification at, for instance, page 8, lines 22-30.

New claims 74 and 75 are supported by the parent specification at, for instance, page 10, line 26 through page 11, line 15.

Substitute Sequence Listing

The substitute sequence listing submitted herewith includes SEQ ID NO:19, which is identical to the SEQ ID NO:4 disclosed in U.S. Patent Application Serial No. 08/727,084 (the '084 application). The present application is a national stage filing of PCT/US97/07725, which

is a continuation-in-part (CIP) of the '084 application. The '084 application was filed October 8, 1996. Thus, SEQ ID NO:19 has a priority date of October 8, 1996.

Rejections under 35 U.S.C. §112, first paragraph

Claim 6 was rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, it was asserted that there is not an adequate description of the genus nucleic acids which are 90% identical with the coding portion of SEQ ID NO:2 and 4. Claim 6 has been amended to delete SEQ ID NO:4, and new claim 69 has been added to recite the subject matter deleted from claim 6. This rejection, as it relates to the pending claims, is respectfully traversed.

Claim 6 has also been amended to recite "wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO:3 or SEQ ID NO:5." Claim 69 also recites the same phrase.

It is respectfully submitted that a person of ordinary skill in the art would not expect substantial variability among the species of nucleic acids encompassed by the scope of the claims because structurally similar nucleic acids result from the requirement that the nucleic acids have at least 90% homology and encode a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO:3 or SEQ ID NO:5. The species disclosed in the specification are representative of the genus because all members have at least 90% homology to the SCA2 coding portion set forth in SEQ ID NO:2 (claim 6) or the SCA2 coding portion set forth in SEQ ID NO:4 (claim 69), and all members encode a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO:3 or SEQ ID NO:5. Thus, one of skill in the art can, as one can do with a fully described genus, recognize the identity of the members of the genus.

It is respectfully submitted that the pending claims comply with the written description

requirement. Accordingly, the Examiner is requested to reconsider and withdraw the rejection of claim 6 under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §102(b)

Claims 1-3, 5, and 62-63 were rejected under 35 U.S.C. §102(b) as being anticipated by Imbert et al. (*Nature Genet.*, 14, 285-291 (1996)). Claims 1 and 5 have been amended to delete "mouse nucleic acid" and "SEQ ID NO:4," respectively, and new claim 65 has been added to recite the subject matter deleted from claim 1. This rejection is respectfully traversed.

Imbert et al. teach the cloning of the human gene for spinocerebellar ataxia 2. Imbert et al. do not teach an isolated mouse nucleic acid encoding an SCA2 polypeptide. Regarding claim 1, it is submitted that Imbert et al. cannot be used as a prior art document against "[i]solated human nucleic acid encoding an SCA2 polypeptide" (claim 1).

SEQ ID NO:1 and SEQ ID NO:2 were disclosed in the '084 application, and have a priority date of October 8, 1996. The genomic DNA from which SEQ ID NO:1 was isolated was human (see, for instance, Example 1 and Example 2 of the '084 application and the present application). SEQ ID NO:2 is a "composite of the human SCA2 cDNA sequence assembled from several overlapping cDNA clones" (page 46, lines 32-34 of the '084 application, and page 47, lines 18-20 of the present application). The first page of Imbert et al. indicates that it was published November, 1996, i.e., after the filing date of the '084 application. Since Imbert et al. was published after the filing date of the '084 application, Imbert et al. cannot be used as a prior art document against "[i]solated human nucleic acid encoding an SCA2 polypeptide" (claim 1).

With respect to the recitation of "[i]solated mouse nucleic acid encoding an SCA2 polypeptide" (new claim 65), Imbert et al. do not teach an isolated mouse nucleic acid encoding an SCA2 polypeptide. Thus, Imbert et al. does not anticipate new claim 65 of the present application.

Regarding claim 5, Imbert et al. cannot be used a prior art document against "nucleotides 1 - 516 of SEQ ID NO:1 or nucleotides 163 - 4098 of SEQ ID NO:2," As discussed above, Imbert et al. was published after the filing date of the '084 application, and the '084 application

discloses SEQ ID NO:1 and SEQ ID NO:2.

With respect to the recitation of "SEQ ID NO:19" (claims 62, 63, and new claim 68), Imbert et al. cannot be used as a prior art document. This sequence was originally disclosed in the '084 application and therefore has a priority date of October 8, 1996. Imbert et al. was published after the filing date of the '084 application.

In view of the above remarks, the Examiner is requested to reconsider and withdraw the rejection of claims the pending claims under 35 U.S.C. §102(b) as being anticipated by Imbert et al.

Claims 1-3, 5-6, and 62-63 were rejected under 35 U.S.C. §102(b) as being anticipated by Pulst et al. (*Nature Genet.*, 14, 269-276 (1996)). Claim 1 has been amended to delete "mouse nucleic acid," and claims 5 and 6 have been amended to delete "SEQ ID NO:4." New claims 65 and 69 have been added to recite the subject matter deleted from claims 1 and 6, respectively. This rejection, as it relates to the pending claims, is respectfully traversed.

Pulst et al. teach the identification of the human SCA2 gene, and disclose at page 275, col. 2, mouse SCA2 cDNA GenBank Accession number U70670. Regarding claim 1, it is submitted that Pulst et al. cannot be used as a prior art document against "[i]solated human nucleic acid encoding an SCA2 polypeptide" (claim 1).

The priority date for SEQ ID NO:1 and SEQ ID NO:2 is October 8, 1996, and as discussed above, these sequences were isolated from human genomic DNA or human cDNA. The first page of Pulst et al. indicates that it was published November, 1996, i.e., after the filing date of the '084 application. Since Pulst et al. was published after the filing date of the '084 application, Pulst et al. cannot be used as a prior art document against "[i]solated human nucleic acid encoding an SCA2 polypeptide" (claim 1).

It is respectfully submitted that Pulst et al. cannot be used as a prior art document against the subject matter disclosed in the present CIP application at the time of filing, including, for instance, the subject matter of new claims 65 and 69. This subject matter was disclosed in PCT/US97/07725, and the present application is a national stage filing of PCT/US97/07725, which has an international filing date of May 8, 1997. Pulst et al. was published less than one

year after PCT/US97/07725 was filed.

Further, Pulst et al. is authored by the inventor. Applicant hereby submits a Declaration by Dr. Stefan-M. Pulst under 37 C.F.R. §132. One of the authors listed on Pulst et al. (Stefan-M. Pulst) is the inventor of the present application. The other 15 authors listed on the Pulst et al. document (A. Nechiporuk, T. Nechiporuk, S. Gispert, X.-N. Chen, I. Lopes-Cendes, S. Pearlman, S. Starkman, G. Orozco-Diaz, A. Lunkes, P. DeJong, G.A. Rouleau, G. Auburger, J. R. Korenberg, C. Figueroa, and S. Sahba) are not inventors of the present application. Because this document was published within one year of the filing date of the PCT/US97/07725 application and the inventor of the claimed invention is also an author of the document, it cannot be properly cited as a prior art document.

Regarding claims 5 and 6, Pulst et al. cannot be used as a prior art document against "nucleotides 1 - 516 of SEQ ID NO:1 or nucleotides 163 - 4098 of SEQ ID NO:2" (claim 5) or "SEQ ID NO:2" (claim 6). As discussed above, Pulst et al. was published after the filing date of the '084 application, and the '084 application discloses SEQ ID NO:1 and SEQ ID NO:2.

With respect to the recitation of "SEQ ID NO:19" (claims 62, 63, and new claim 68), Pulst et al. cannot be used as a prior art document. This sequence was originally disclosed in the '084 application and therefore has a priority date of October 8, 1996. Pulst et al. was published after the filing date of the '084 application.

In view of the above remarks, the Examiner is requested to reconsider and withdraw the rejection of the pending claims as being anticipated by Pulst et al.

Claims 5-6 and 62-64 were rejected under 35 U.S.C. §102(b) as being anticipated by Gispert et al. (*Nature Genet.*, 4, 295-299 (1993)). This rejection, as it relates to the pending claims, is respectfully traversed.

Gispert et al. teach the assignment of the human autosomal dominant cerebellar ataxia SCA2 to chromosome 12q23-24.1. Gispert et al. do not teach the nucleotide sequence of the human autosomal dominant cerebellar ataxia SCA2 at chromosome 12q23-24.1.

Although it was not made explicit, it appears that this rejection is based on the doctrine of inherency. Specifically, it appears that this rejection is based on the allegedly inherent properties

of the nucleotide sequence of chromosome 12q23-24.1 disclosed by Gispert et al. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P §2112 (emphasis in original). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P §2112 (emphasis in original). It is respectfully submitted that the Examiner has not met her burden of providing a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the cited documents.

Claims 5-6 and 62-64 were rejected under 35 U.S.C. §102(b) as being anticipated by Pulst et al. (*Nature Genet.*, 1, 8-10 (1993)). This rejection, as it relates to the pending claims, is respectfully traversed.

Claims 5 and 6 depend upon claim 2, which in turn depends upon claim 1. Claim 1 recites an isolated mouse or human nucleic acid encoding an SCA2 polypeptide. Claims 62-64 recite, inter alia, an isolated nucleic acid, wherein the isolated nucleic acid encodes an SCA2 polypeptide. Pulst et al. do not teach an isolated nucleic acid encoding an SCA2 polypeptide. Pulst et al. teach the identification of a human pedigree with linkage to 12q and establishment of flanking markers for SCA2. As Pulst et al. do not teach an isolated nucleic acid encoding an SCA2 polypeptide, Pulst et al. do not anticipate the claims of the present invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claim 7 was rejected under 35 U.S.C. §103 as being unpatentable over Imbert et al. (*Nature Genet.*, 14, 285-291 (1996)) or Pulst et al. (*Nature Genet.*, 14, 269-276 (1996)) in view of Orr (U.S. Patent 5,741,645). Claim 7 depends upon claim 1, which has been amended to delete "mouse nucleic acid." New claim 70 has been added to recite the subject matter deleted from claim 7. This rejection, as it relates to the pending claims, is respectfully traversed.

As discussed above, since Imbert et al. was published after the filing date of the '084

application, Imbert et al. cannot be used as a prior art document against "[i]solated human nucleic acid encoding an SCA2 polypeptide" (claim 1). Since claim 7 depends from claim 1, Imbert et al. cannot be used as a prior art document against claim 7.

As discussed above with respect to claims 65 and 69, Pulst et al. should not be considered a prior art document because Pulst et al. was published within a year after the international filing date of PCT/US97/07725 and Pulst et al. is authored by the inventor. Since claim 70 depends from claim 65, Pulst et al. cannot be used as a prior art document against claim 70.

Since the two secondary documents used in this rejection are not prior art documents for claim 7 and claim 70, the Examiner is requested to reconsider and withdraw the rejection of claim 7 as being unpatentable under 35 U.S.C. §103.

Conclusion

It is respectfully submitted that the pending claims, 1-3, 5-7, 59, and 61-75, are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,
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Date of Deposit: September 12, 2001
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APPENDIX A

SPECIFICATION / CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE

Applicant(s): Stefan M. Pulst
Serial No. 08/981,998
Filed on 11 May 1998
NUCLEIC ACID ENCODING SPINOCEREBELLAR ATAXIA-2
AND PRODUCTS RELATED THERETO
Attorney Docket No. 256.00010120

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments and newly added claims have been bolded.

In the Claims

For the Examiner's convenience, all of the pending claims are shown below.

1. (Twice Amended) Isolated **[mouse or]** human nucleic acid encoding an SCA2 polypeptide.

2. Isolated nucleic acid according to claim 1, wherein said nucleic acid comprises DNA.

3. DNA according to claim 2, wherein said DNA is cDNA.

5. (Amended) DNA according to claim 2, wherein said DNA hybridizes under high stringency conditions to the SCA2 coding portion of nucleotides 1 - 516 of SEQ ID NO:1 or nucleotides 163-4098 of SEQ ID NO:2 **[, or nucleotides 50-3454 of SEQ ID NO:4]**.

6. (Twice Amended) DNA according to claim 2, wherein said DNA has at least

90% homology to the SCA2 coding portion set forth in SEQ ID NO:2 **[, or the SCA2 coding portion set forth in SEQ ID NO:4]** **wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO:3 or SEQ ID NO:5**.

7. A vector comprising DNA according to claim 2.

59. An isolated nucleic acid encoding the amino acid sequence set forth at SEQ ID NO:5.

61. (Twice Amended) **[The]** **An** isolated nucleic acid **[of claim 1, wherein the nucleotide sequence is]** set forth at SEQ ID NO:4 **encoding an SCA2 polypeptide**.

62. (Amended) An isolated nucleic acid, wherein the nucleic acid hybridizes under high stringency conditions to nucleotides 1 - 516 of SEQ ID NO:1, nucleotides 163-4098 of SEQ ID NO:2, or **[nucleotides 50-3454 of SEQ ID NO:4]** **SEQ ID NO:19**, wherein the isolated nucleic acid encodes an SCA2 polypeptide.

63. (Amended) An isolated nucleic acid, wherein the nucleic acid hybridizes under high stringency conditions to **[nucleotides 50-3454 of SEQ ID NO:4]** **SEQ ID NO:19**, wherein the isolated nucleic acid encodes a fragment of an SCA2 polypeptide.

64. An isolated nucleic acid, wherein the nucleic acid hybridizes under high stringency conditions to nucleotides 1 - 516 of SEQ ID NO:1, or nucleotides 163-4098 of SEQ ID NO:2, wherein the isolated nucleic acid encodes an SCA2 polypeptide.

65. (New) Isolated mouse nucleic acid encoding an SCA2 polypeptide.

66. (New) Isolated nucleic acid according to claim 65, wherein said nucleic acid comprises DNA.

67. (New) DNA according to claim 6, wherein said DNA is cDNA.

68. (New) DNA according to claim 66, wherein said DNA hybridizes under high stringency conditions to the SCA2 coding portion of SEQ ID NO:19.

69. (New) DNA according to claim 66, wherein said DNA has at least 90% homology to the SCA2 coding portion set forth in SEQ ID NO:4 , and wherein the DNA encodes a polypeptide that binds to an antibody, the antibody produced using an amino acid sequence selected from the group consisting of SEQ ID NO:3 or SEQ ID NO:5.

70. (New) A vector comprising DNA according to claim 66.

71. (New) An isolated nucleic acid comprising nucleotides 163-4098 of SEQ ID NO:2.

72. (New) An isolated nucleic acid encoding the amino acid sequence set forth at SEQ ID NO:3.

73. (New) An isolated nucleic acid comprising nucleotides 50-3454 of SEQ ID NO:4.

74. (New) An isolated nucleic acid set forth at SEQ ID NO:19.

75. (New) An isolated nucleic acid comprising the nucleic acid sequence set forth at SEQ ID NO:19.